

**In The United States District Court
Southern District of Ohio**

In re: Ohio Execution Protocol Litigation,	Case No. 2:11-cv-1016 Judge Edmund Sargus, Jr. Magistrate Judge Michael Merz
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**Reply in Support of Motion to Quash Subpoena Issued to
Interested Party Ohio State Board of Pharmacy**

I. Discovery Regarding Terminal Distributors.

In its motion, the State of Ohio Board of Pharmacy (“the Board”) argued that further discovery about the process for a terminal distributor of dangerous drugs (TDDD) to obtain a license was unnecessary because (1) the Board provided the documents that Plaintiff Jackson requested, and (2) the requirements to obtain a TDDD is a legal issue, not a factual one.

Plaintiff Jackson has responded by insisting that, at a previous hearing, a witness had raised an issue “about the Board’s licensure procedures or how easily a TDDD or wholesaler’s license could be obtained.” Rec. 2207, PageID 106951. The Board will take Plaintiff Jackson at his word that this is an issue of controversy.

The answers to these questions are found in the documents that the Board provided (i.e. the applications) and the state law provisions which establish that an entity will be eligible for a TDDD license if it meets the minimum requirements and there are no administrative prohibitions; and if

there is a question about those prohibitions, then the TDDD will be entitled to an administrative hearing. An entity desiring to be licensed in Ohio as a TDDD need only apply and meet the minimum qualifications, unlike other types of licenses that are limited and competitive in nature. There is no maximum number of TDDD licenses either in-state or out-of-state the Board can issue. Thus, the issue of obtaining a TDDD is a legal matter rather than a factual one. The same holds true for a wholesaler. No further discovery is necessary.

On a related note, Plaintiff Jackson and the Board disagree about whether the Board has provided a list of which TDDEs stated on their renewal paperwork that they performing sterile compounding of controlled substances. According to Plaintiff Jackson, the list provided by the Board was for TDDEs that do *any* compounding. Plaintiff Jackson only wants the list to be those TDDEs that do sterile compounding of controlled substances (which he insists will be a narrower list); however, that list does not exist.

In an effort to be helpful, the Board provided an excel list of *all* active TDDE licenses with columns Y & Z containing compounding information. That is the information the Board had in 2015 when it provided an earlier list and that is the information the Board has now. To identify TDDEs that report that they compound and have the ability to compound controlled substances, Counsel for Plaintiff Jackson can do the following: sort the Excel spreadsheet provided to only include “Category 3” TDDEs (column B) (this

will identify TDDDs that have authority to handle controlled substances) and further sort by whether the TDDD reports compounding (column Y).

It is difficult to see how Plaintiff Jackson has been prejudiced by getting *more* information than he requested. Indeed, many of the medications on Plaintiff Jackson's list of drugs that could be used for lethal injection are *not* controlled substances. Under Ohio and federal law; only those dangerous drugs with a potential for abuse receive a controlled substance designation. In the list provided by Plaintiff Jackson in the subpoena, the following are not controlled substances: propofol, etomidate, rocuronium bromide, pancuronium bromide, vecuronium bromide and potassium chloride. *See* 21 U.S.C. §812, 21 C.F.R 1308.11 *et seq*, and R.C. 3719.41.

The Board provided an Excel spreadsheet of all TDDDs that have reported engaging in compounding medications. This will include TDDDs that can compound non-controlled substances such as pancuronium bromide, but are not permitted to compound controlled substances like morphine. The Board can hardly be faulted for providing this information.

Plaintiff Jackson appears to misunderstand one argument raised by the Board. The Board has consistently said it that would provide to Plaintiff Jackson, even without a subpoena, a list for TDDDs that report that they do compounding. It did so. The Board does not have a list for *pharmacists* (i.e. the people who work at TDDDs) who do compounding. Even if a list of

individual pharmacists who compound medications existed (and it does not), the issue raised in the prior case was not about the difficulty in getting a license as a pharmacist – it was about the difficulty of getting a license as a TDDD.

II. The Court Should Quash All Inquiries Into Any Board Investigations of Diversion of Drugs.

The Board argued in its motion that discovery about diversion of opioids and benzodiazepines was wildly overbroad and unlikely to lead to the discovery of admissible evidence. The subpoena issued to the Board about diversion requested *all* reports and investigations for an 8 year period “regarding drugs that Ohio has used or could use to carry out human executions by lethal injection.” Plaintiff Jackson defined that list of drugs that “has used or **could use** to carry out human executions” as including every barbiturate, opioid, and benzodiazepine. Although Plaintiff Jackson included a specific list of individuals and organizations, the text of the subpoena required “any other reports similarly required by state or federal law concerning controlled substances that Ohio has used or could use to carry out human execution by lethal injection.” The request was not limited to DRC and its employees.

The Board pointed out that the subpoena as written would require the Board to turn over a staggering number of documents regarding investigations that have nothing at all to do with lethal injection. And it would require the Board to turn over reports which are submitted by WDDDs

and TDDDs into the OARRS database – which is confidential under state and federal law.

In the opposition, Plaintiff Jackson has either narrowed or clarified the scope of his subpoena. It appears that Plaintiff Jackson is essentially returning to what had been requested during the lethal injection litigation in 2015 – to provide copies of documents from any Board investigation into DRC or its staff members regarding lethal injection. In 2015, the Board stated in its response that there had been investigations regarding DRC between 1998 until 2015, but none of them involved lethal injection.¹ A copy of the 2015 subpoena and the Board's response is attached.

Before going on, one point needs to be emphasized. When Plaintiff Jackson is discussing “diversion” he is implicitly referring to a statutory provision which requires the Board to promulgate regulations to “[f]acilitate surveillance of traffic in drugs, to prevent the improper acquisition or use of controlled substances or their ***diversion into illicit channels.***” R.C. 3719.18(A)(1) (emphasis added).

DRC's use of medications to carry out lethal injection is not an “illicit channel” under Ohio law. The Ohio General Assembly has given statutory

¹ Much of Plaintiff Jackson's response revolves around the communications between counsel. The Board will not get into a tit-for-tat refutation, but it wants to emphasize that Plaintiff Jackson has never expressly limited or modified the scope of his subpoena. Also, it is unreasonable for a party to give a non-party one business day to raise any concerns. Counsel for Plaintiff Jackson sent an ultimatum by e-mail on a Friday (April 26) requiring the Board to provide a response by 2 p.m. on Monday (April 29). Setting such unreasonable time limits will hinder amicable resolution of discovery disputes – especially with a non-party.

authority to DRC to carry out executions by using lethal injection. R.C. 2949.21, 2949.22, 2949.221 and 2949.24.

State agencies in Ohio (including the Board) are “creature[s] of the General Assembly and may exercise no jurisdiction beyond that conferred by statute.” *Penn Cent. Transp. Co. v. Pub. Util. Com.*, 35 Ohio St.2d 97, syllabus paragraph 1 (1973). It has been black letter law for over half a century that state agencies in Ohio do not have statutory authority to declare Ohio statutes to be unconstitutional. *See S. S. Kresge Co. v. Bowers*, 170 Ohio St. 405, syllabus paragraph 1 (1960); *Castle Aviation, Inc. v. Wilkins*, 109 Ohio St.3d 290, 296, 2006-Ohio-2420. Nor does the Board have authority to overrule the conclusions of the Ohio Supreme Court and the United States Supreme Court that lethal injection is not categorically barred as a lawful method to carry out executions. *See Baze v. Rees*, 553 U.S. 35 (2008); *State v. Broom*, 146 Ohio St.3d 60, 2016-Ohio-1028.

In short, as a matter of Ohio law, there is no “diversion into illicit channels” if DRC obtains medications to perform its lawful duty to perform executions using lethal injection. Thus, any challenge to this activity would require a finding that Ohio statutes authorizing lethal injection are unconstitutional – a power that the Board simply does not have.

In other words, Plaintiff Jackson is seeking discovery to prove that a non-party is not performing investigations into something that – under state law – is perfectly legal. There is not a reasonable likelihood that such an

avenue will lead to the discovery of admissible evidence. The Court should quash the subpoena to the extent that it seeks documents or testimony about the Board's investigations into potential diversion of controlled substances.

Even if Plaintiff Jackson should be able to obtain discovery, the current subpoena is so broadly written that it either needs to be rewritten by Plaintiff Jackson or the Court needs to spell out very specific parameters as to what the Board needs to provide as documents and what subjects will be available for testimony. Either way, discovery against the Board regarding diversion should be limited *only* to potential investigations of the DRC or its staff regarding how executions are carried out.

III. The Court Should Quash Any Production Of Documents From the OARRS Database.

In its motion to quash, the Board pointed out that the "reports" that Plaintiff Jackson is requesting are all submitted by TDDDs and WDDDs into the OARRS database pursuant to Ohio Adm. Code 4729:8-3-01(C) and (D).

Plaintiff Jackson responds by insisting that he is not seeking any individual patient's OARRS records. That is all well and good, but the fact is that TDDDs and WDDDs input *their* reports about suspicious activities into OARRS and information in the OARRS database is confidential under state and federal law – a point that Plaintiff Jackson does not dispute. The Court should quash the subpoena to the extent that it requires production of documents from the OARRS database.

IV. Production of A Certification

Plaintiff Jackson lambasts the Board for refusing to provide a certification, insisting that such a document would be *de minimis*.

What Plaintiff Jackson does not say is that the Board *did* provide a certificate that would meet any requirements necessary for Plaintiff Jackson to authenticate during a hearing the records provided. A copy of that document is attached.

What the Board did not provide was a document certifying that it had completed its search for responsive documents and had provided all of them.

Such a declaration is premature. As the Board explained in the motion to quash, the scope of the discovery requests was staggeringly large. The Board reasonably sought to limit the scope of discovery – especially because it is a non-party – by filing a motion with this Court.

The Board will not be in a position to search for responsive documents with regards to the diversion issues until this Court more clearly identifies the scope of the subpoena and whether documents in the OARRS database are confidential.

A non-party should not be faulted for refusing to falsely sign a declaration claiming it has completed a review for all responsive documents when it raised good faith arguments about what should be the scope of the subpoena.

Respectfully submitted,

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Certificate of Service

A copy of the foregoing was served on all counsel by operation of this
Court's electronic filing system.

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